



# The Association of State Wetland Managers, Inc.

"Dedicated to the Protection and Restoration of the Nation's Wetlands"

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1200 Pennsylvania Avenue NW  
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**Docket ID No. EPA-HQ-OA-2018-0259**

**Re: Strengthening Transparency in Regulatory Science**

To Whom It May Concern:

These comments were prepared by the Association of State Wetland Managers (ASWM) in response to the April 30, 2018 *Federal Register* notice "Strengthening Transparency in Regulatory Science." ASWM represents states and tribes in promoting the sound management of wetlands and other waters. Our technical support of states and tribes includes state and federal dredge and fill permit programs including § 404 of the Clean Water Act; development of water quality standards for wetlands; § 401 Certification of federal permits and licenses; and coordination with other state and federal programs impacting aquatic resources. Thus, although we recognize the broad scope of the proposed regulation, our comments are focused on the potential impact of the proposed rule on these areas of public policy.

We are cognizant that discussion of this proposed rule has focused on the impacts of environmental contamination on public health. However, the rule as written is very broad, and also clearly extends to other CWA programs. CWA §104 – which authorizes environmental surveillance and monitoring for a wide array of programs – is included in the legislative provisions used to justify the rule. The definition of "*dose response data and models*" included in the proposed rule directly refers not only to public health but also to environmental impact. Therefore, we anticipate that the proposed rule would directly alter the programs of interest to our member states.

The stated intent of the proposed rule is "to strengthen the transparency of EPA regulatory science" by "ensuring that the data underlying [pivotal regulatory decisions] are publicly available in a manner sufficient for independent validation." ASWM strongly agrees that environmental regulatory decisions should be based on the best available science, including both peer-reviewed science and other pertinent information. However, we are greatly concerned that the proposed rule would unnecessarily limit the use of available sound science to an extent that would undermine EPA's mission to protect public health and the environment. We question whether there is a need for greater public access to raw data, given the extensive measures already in place to ensure scientific transparency.

## GENERAL COMMENTS

- **Ambiguity of the proposed rule.** ASWM finds it difficult to predict the effect of the proposed transparency rule given the broad and general nature of the described intent and applicability, and lack of information regarding how it would be implemented in practice. It is impossible based on the information provided in the *Federal Register* notice to fully evaluate the potential demand on time and agency resources, and to ascertain the benefits or impediments that might result from the proposed regulation. We are concerned that the notice fails to provide sufficient detail for an analysis of whether the new approach will achieve the stated purpose without creating unintended consequences that make it difficult for states to implement clean water programs.
- **Role of Science in Decision Making.** One of the most important factors in decision-making associated with environmental issues and public health is the application of sound science. While other factors such as economics, public values, availability of technology, coordination with other laws and programs etc., are important to consider, it is science that is the most transparent and that should provide the foundation for decision makers. The application of sound science results in a fact-based decision and supports consistency and predictability in regulatory actions. It also allows decision makers to more clearly articulate and defend their decisions.
- **Need for the proposed rule.** EPA solicits comments on how this proposal can be “promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.” In fact, ASWM believes that the Federal programs that are the province of our members already provide sufficient opportunities for public review and analysis. This is in addition to the rigorous peer review provided by the scientific publications. We therefore question the need for the rule. We find the justification for the proposed rule – the statement that “*EPA has not previously implemented [policy and guidance that has called for increasing public access to data] in a robust and consistent manner*” -- to be unconvincing. If the issue is with implementation rather than the underlying policies and guidance, then a new rule is not what is needed.

We suggest that EPA provide documentation of the inability of the public to review important data, and the resulting environmental impact. We also request examples of how additional review by the public could improve the regulatory process without adding an unacceptable cost or delay, and/or excluding information essential to the validity of decision making.

Existing published literature often plays a role in decision making and predicts environmental and economic impacts. Scientific journals typically have a peer review system in place to evaluate the soundness of the research submitted for publication. It is unclear when and why use of this type of information would require more transparency, as methods of data collection and analysis are clearly described to inform the results and conclusions.

- **Potential impact on third parties and grantees.** The proposed rule applies to scientific data gathered by third parties and grantees. EPA grant funding supports the efforts of states to conduct research and carry out their own respective regulations. It is unclear how this regulation would impact science gathered and applied independently by the states. Grant recipients are required to document their approaches for

data collection and analysis, and overall quality control. ASWM recommends that the sufficiency of existing approaches be fully considered before making substantive changes. ASWM further recommends that adequate safeguards be considered in any proposed rules to protect personal information of relevant parties.

- **Consistent treatment of data regardless of source.**

ASWM notes that the proposed rule applies to the transparency of data used by federal agencies in rule and decision making. We recommend that federal agencies apply the same stringent standards for transparency and quality of data to all information used in decision-making regardless of its source, that is, whether provided by public agencies, the academic community, regulated entities, or other sources. Moreover, we believe that scientific transparency would be increased by requiring information regarding the entity providing financial support for the related research. Funding by federal agencies and many foundations are typically identified in research reports, but corporate and other private funders may not be. Given that funding entities may influence the formulation of scientific questions raised by the research, this information is necessary to fully understand the conclusions that may be drawn from the research.

## **RESPONSE TO REQUEST FOR COMMENTS IN SECTION III OF *FEDERAL REGISTER* NOTICE.**

### **1. Effect of the proposed rule on individual programs.**

- **Clean Water Act definition of Waters of the United States (WOTUS).**

The proposed rule language indicates that it is generally applicable prospectively to final agency actions. However, the agencies also request comments on applicability to other stages of rulemaking. EPA is currently engaged in a very extended proposed modification to the definition of Waters of the United States (WOTUS). ASWM continues to urge expedited resolution of the various proposed revisions to the definition of WOTUS and it is unclear how the proposed rule might affect current rulemaking efforts.

Although the definition of “*dose response data and models*” may not apply directly to the WOTUS rule, the *Federal Register* notice also indicates that EPA is considering expansion of the rule “*to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulation interventions on complex economic or environmental systems.*” Given the in-depth scientific analysis undertaken to support development of the 2015 rule regarding WOTUS – based heavily on a publicly available analysis of the pertinent peer-reviewed literature – ASWM recommends completion of the WOTUS rule using the existing scientific analysis. That is, we recommend that the WOTUS rule be exempted from any application of the proposed rule regarding transparency in science. Applying the proposed rule to the information gathered to support a WOTUS rule is unnecessary given currently availability of the underlying science to the public.

- **Water Quality Standards.**

It is unknown how the proposed rule would impact development of Water Quality Standards for wetlands. Please note that many states include pollutant and toxic discharge standards

among those that are applied to wetlands. The proposal should clearly address and answer this question, and also clarify the impact on grants to states.

- National Environmental Policy Act.

The Administration is currently engaged in a multi-year effort to streamline NEPA. ASWM recommends that the proposed rule not undermine that initiative either by excluding information that does not meet the requirements or by requiring more time for the required transparency standards to be met.

## **2. Request for comments regarding the scope of the proposed regulation.**

ASWM has based this set of comments on our understanding that the text of the proposed rule would apply to a “significant regulatory action” as defined in E.O. 12866. That definition reads as follows:

*“...any regulatory action that is likely to result in a rule that may:*

*(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;*

*(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;*

*(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or*

*(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order.*

- **Should the proposed rule be expanded “...to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulation interventions on complex economic or environmental systems.”**

ASWM supports the use of numerous types and sources of data and information in decision-making. Particularly where legal standards require consideration of a wide array of factors in reaching a regulatory decision - including not only ecological and economic factors, but practicality and alternatives to the proposal, secondary impacts, and other criteria - many types and sources of data are routinely necessary for a sound decision. However, data requirements are already defined in the rules and guidance associated with specific regulatory programs; such information is already subject to public review both in rule-making and in other program decisions such as permit approval. Use of the broadest possible range of information increases the validity and accuracy of decisions and should not be limited by overly burdensome requirements as described by the proposed rule.

- **Should the requirements in the proposed rule also apply to, “... other stages of the rulemaking process...as well as to other types of agency actions and promulgations, such**

**as guidance.”**

ASWM believes that applying such strenuous requirements for data early in the development of a rule would restrict initial consultation with other agencies, with stakeholders, and with the public. We see no valid reason to impose such restrictions.

ASWM also opposes application of the requirements of the proposed rule to promulgation of guidance. In environmental programs, guidance often supports implementation of a rule in a practical manner at the field level. As such, it may explain how to accurately and effectively apply regulations in different geographic areas, or under other conditions that may vary from site to site such as specific soil conditions. Practical, accurate, and efficient application of regulations in the field typically depends upon guidance based not only on published science, but also on professional experience and results of field testing. It would be highly impractical to make such information available to the public in the format described by the proposed rule. On the other hand, failure to develop guidance because of lack of extensive published data would cripple implementation of necessary regulatory programs.

- **Should the scope of coverage by the proposed rule be narrowed.**

In general, we support significant narrowing of the scope of the proposed rule, if it is finalized. EPA should define a more specific category of decisions that demand the level of public access to data defined by this rule, and more fully explain how the benefit of greater public access to raw data justifies the cost of implementation.

EPA has suggested only that the scope be limited to a “major” decision under the Congressional Review Act – which is defined as “economically significant under E.O. 12866”; or, alternatively, to a regulation found to be “economically significant” under E.O. 12866 – which is essentially the same thing. ASWM fails to understand the distinction among these criteria, and that proposed in the rule. We request clarification.

- **Should the provisions of the proposed rule apply to, “*individual party adjudications, enforcement actions, or permit proceedings that EPA determines are scientifically or technically novel or likely to have precedent setting influence on future actions.*” Should “...other agency actions... such as site-specific permitting actions or non-binding regulatory determinations” be included.**

While ASWM has concerns regarding the impact of the proposed rule in decisions on rulemaking, we have even *greater* concerns regarding the suggested application of the proposed rule to individual permit actions. Such requirements would be grossly inconsistent with sound and timely authorizations under the §404 dredge and fill permit program in particular.

Tens of thousands of actions – including numerous dredge and fill construction activities undertaken both by private landowners and public agencies – are authorized annually under §404 of the CWA, through the collaboration of EPA, the U.S. Army Corps of Engineers, and the states and tribes. The expeditious review and issuance of authorizations under this program is essential for the range of projects authorized under §404. Moreover, data collected and submitted by the applicant to support the decision, and by the regulatory agencies to inform the

decision, are both essential and collected on a case-by-case basis as needed. The level of detail of a permit specific analysis is generally commensurate with the scope of a particular project (e.g. repair of a private seawall, versus construction of an interstate highway). Regulations that subject all data to identical requirements regarding data collection, evaluation, and release would interfere with the permitting process in an unacceptable manner.

Under §404, the vast majority of permits are issued by the U.S. Army Corps of Engineers through general permits. Many associated state programs include statutory deadlines for review and approval. Thus, any delay associated with re-review of original supportive data beyond what is already provided for in the public notice process would have the effect of slowing and delaying these authorizations, at a significantly increased regulatory cost. Moreover, the exclusion of non-peer reviewed data - which is typically collected at the time of a permit application for the purpose of clarifying both the extent and limitations of adverse impacts - would undermine the accuracy of individual permit decisions. Finally, ASWM notes that there are existing options for appeal and legal recourse for applicants or permittees to question the validity of scientific data used in decision making; therefore, there is no need to apply the proposed provisions to individual cases.

### **3. Should the proposed rule apply retroactively to data collected prior to the effective date of the rule.**

It is difficult to envision how the proposed rule could be applied retroactively to the science developed through long term experience in the implementation of various regulations and standards. Exclusion of research that was accepted as scientifically valid in the past could only result in the need to duplicate such research, adding needless cost and delay to the process of decision making. ASWM objects to this concept.

Current regulations under the CWA have evolved over decades, supported by extensive peer reviewed science and other data collected by federal agencies, state and local agencies, academic institutions, stakeholders, and the general public. Supporting data includes the results of long-term monitoring of the impact and effectiveness of previous regulations, thereby supporting adaptive management and adjustments needed to address those impacts. Reports of such studies are readily available.

### **4. Request for comments on additional implementation challenges.**

The proposed rule itself could be defined as a “significant regulatory action” under E.O. 12866 based both on the cost to implement the action (that is, to subject all agencies and organizations that provide data to EPA to the provisions of the proposal), and on the fact that the rule could, *“...create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.”* We suggest that EPA develop a comprehensive cost-benefit analysis to support this action, reflecting both the full benefit of resources protected, and the cost of any resulting delay in execution of regulatory actions.

The Congressional Budget Office consulted with EPA in recent analyses of related legislation, H.R. 1030 in 2015, and H.R. 1430 in 2017. The 2015 analysis determined that the agency would need to expend \$250 million/year initially in implementation of the measure, even if the number of studies that EPA relied on was reduced by one half. The CBO determined that meeting the H.R. 1430 requirements would cost EPA an average of \$10,000 per study.

**5. Comments regarding the proposed authority of the Administrator to exempt regulatory decisions from the rule.**

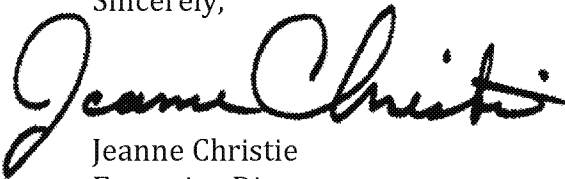
The proposed rule gives the EPA Administrator the authority to “exempt significant regulatory decisions on a case-by-case-basis” from the requirements of this new subpart. This appears to give EPA Administrators a great deal of discretionary authority now and in the future pursuant to the implementation of this rule. It is unclear why an exemption from compliance with the rule would be needed if the final rule is not excessively burdensome; how that discretionary authority will be exercised; and what, if any, standards would be applied by the Administrator in determining exemptions. In our experience, consistent application of regulations and standards is necessary to provide the clarity and predictability needed in carrying out science-based programs. This authority could be applied very differently over time as EPA leadership changes, with unintended consequences for applicant clarity or sound management of environmental resources.

**SUMMARY**

Given the broad scope and potential effect of the proposed rule, we recommend that an additional step be added for EPA to hold discussions with impacted states and tribes and other stakeholders to provide supplemental information to the current proposal. We also request that EPA provide a supplement to the rule to explain more fully how the proposed rule would increase transparency without delaying decision-making or excluding consideration of traditionally acceptable data and publications, given the numerous federal provisions already in place to achieve the goal of ensuring transparency.

As always, we appreciate the opportunity to review and comment on this proposal. While these comments have been prepared with input from the ASWM Board of Directors, they do not necessarily represent the individual views of all states and tribes; we therefore encourage your full consideration of the comments of individual states and tribes and other state associations. Please do not hesitate to contact me should you wish to discuss these comments.

Sincerely,

A handwritten signature in black ink, reading "Jeanne Christie". The signature is fluid and cursive, with the first name "Jeanne" and last name "Christie" clearly distinguishable.

Jeanne Christie  
Executive Director

Cc: Mr. Tom Sinks, Office of the Science Advisor, USEPA  
ASWM Board of Directors  
Marla Stelk, ASWM